Released 01/14/00. Approved by NCI ACUC.

Instructions for Using the Adobe Acrobat Version of the NCI Animal Study Proposal Form

Technical Information

The NCI Animal Study Proposal Form was created using Adobe Acrobat. You must have Adobe Acrobat Reader version 4.0 in order to use this form.

The proposal form was designed with each page of the form as an individual layout, therefore each proposal will be a separate database with only one record. An original form with signatures by the principal investigator and lab/branch chief must be submitted to Building 31, Room 4A34 for committee review and approval. For studies to be conducted at FCRDC, the form should be submitted to the FCRDC-ACUC, Building 428, Room 52.

Security and Renaming the proposal form

A blank copy of the form should be retained for future use, therefore;

1. Download the file onto your hard drive and open "NCIASP.PDF."
2. Each time form is opened immediately go to the menu, under file, select "Save a copy as..", and name your proposal.
3. Open the renamed proposal form.

Moving through the proposal form

To move from page to page, simply scroll up or down. Fields have been inserted into each page. You will have to find one field wih your cursor to move from field to field. To move from field to field, hit the TAB key. To back up, hold the SHIFT key down while hitting the TAB key.

Entering Text

There are continuation pages for Sections B, C, D, E, F1, F4, F5, G, and H. Scroll to the appropriate blank continuation page. There are no stops or warnings for entering too much text outside the field, therefore you have to notice when you need to go to the continuation pages. The program won't lose the text, but it will not print it. If you happen to extend outside the section field, highlight the additional text with the mouse, copy it, and paste the text in the continuation page.

WARNING - For the program to accept data, you must move to another field.

Printing

To print, hold down the COMMAND key and P or select PRINT from the FILE menu.

Technical Support

If you need help or have comments , please call Bill Hinkle at 496-1866.

GUIDELINES FOR PAIN/DISTRESS CLASSIFICATION
(For guidance only in categorizing animal use in Part G.)

DEFINITIONS:

PAIN is awareness of acute or chronic discomfort occurring in varying degrees of severity resulting from injury, disease, or emotional distress and evidenced by biological or behavioral changes or both.

ACUTE PAIN results from a traumatic, surgical, or infectious event that is abrupt in onset, relatively short in duration, and generally alleviated by analgesics. Associated distress may be responsive to tranquilizers.

CHRONIC PAIN results from a long standing physical disorder or emotional distress that is usually slow in onset, has a long duration, and is generally not totally alleviated by analgesics, but frequently responds to tranquilizers combined with environmental manipulation and behavioral conditioning.

DISTRESS is undesirable physical or mental stress resulting from pain, anxiety, or fear. Its acute form may be relieved by tranquilizers, while sustained distress requires environmental change or behavioral conditioning, and does not respond to drug therapy.

CATEGORY 1 - MINIMAL, TRANSIENT, OR NO PAIN OR DISTRESS

These procedures are considered to produce minimal, transient or no pain or distress when performed by competent individuals using recognized methods.

1. Administration of:
   a. Anesthetics, analgesics, and tranquilizers
   b. Fluid and electrolyte therapy
   c. Immunizations including the proper use of Complete Freund's Adjuvant
   d. Oral medications
2. Non-chronic catheterization
3. Blood collection. This includes periorbital withdrawals in species with a true orbital sinus (mice), but excludes intra cardiac blood collection. (NOTE: Periorbital blood withdrawal from unanesthetized animals is discouraged.)
4. Oral gavage
5. Certain manipulative procedures such as injections, palpations, skin scrapings, tail biopsies, and radiography.
6. Euthanasia as performed in accordance with recommendations of the AVMA Panel on Euthanasia that produces rapid unconsciousness and subsequent humane death with minimal or no pain or distress (inhalant anesthetics, CO_2, parenteral barbiturates).
7. Intracerebral inoculations in neonatal rodents prior to cranial ossification when performed by trained personnel.
8. Chair restraint of an adapted nonhuman primate.

If the result of any of the above procedures is painful or distressful, the procedure should be listed under Category 2 or Category 3 below.

CATEGORY 2 - PAIN AND DISTRESS RELIEVED BY APPROPRIATE MEASURES

Examples of procedures that may produce pain or distress, but which are performed using appropriate and adequate anesthetics, analgesics, or tranquilizers and followed with appropriate measures to alleviate pain or distress are as follows:

1. All surgery, including biopsy, gonadectomy, and neurophysiological manipulations or preparation such as implantation of electrodes and recording devices.
2. Terminal surgical procedures in which the animal(s) are euthanized before recovering from anesthesia.
3. Periorbital collection of blood in species without a true orbital sinus (rats and guinea pigs).
4. Intra cardiac blood collection.
5. Euthanasia performed in accordance with recommendations of the AVMA Panel on Euthanasia that would involve pain or distress if anesthetics, analgesics, analgesics or tranquilizers were not used (pithing in certain species, or exsanguination).
6. Monoclonal Antibody Production using the ascities method.

CATEGORY 3 - UNRELIEVED PAIN OR DISTRESS

Procedures which are performed without appropriate and adequate anesthesia, analgesia, or tranquilizers or which are not followed with appropriate measures to alleviate pain or distress, or which are not amenable to relief by therapeutic measures, must be listed in Category 3. Examples include:

1. The chairing of a nonhuman primate not conditioned for the time period of restraint.
2. Drug or radiation toxicity testing producing unrelieved pain and distress.
3. LD_{50} determinations.
4. The exposure of an animal to an agent which produces unrelieved pain and distress.
5. The exposure of an animal to electric shocks that are generally accepted as causing pain in humans.

PRINCIPAL INVESTIGATORS: INSTRUCTIONS FOR COMPLETING THE NCI ANIMAL STUDY PROPOSAL FORM (NIH-2643-1, REV. 12/99)

PHS Animal Welfare Policy and the Animal Welfare Act require review and approval of an Animal Study Proposal by the Animal Care and Use Committee (ACUC) prior to the conduct of any activity involving vertebrate animals.

GENERAL INSTRUCTIONS:

- Please type. Handwritten forms are not acceptable.
- Fill in **each** space. Incomplete proposals will be returned for completion before processing.
- All information in this proposal is considered privileged and confidential by the ACUC and the concurring authorities; however, approved proposals are subject to release under the Freedom of Information Act.
- The information in this proposal should represent a plan for the research to be conducted. It will be evaluated to assure that the animals will be treated humanely and that appropriate facilities and technical assistance are available to support the research.

References: URL http://camp.nci.nih.gov/science/olar/asb/ncipolcy/plcytab.htm

1. Guide for the Care and Use of Laboratory Animals, revised 1996.
2. Animal Welfare Regulations, 9CFR, Parts 1, 2, and 3.
3. "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training." 1985.
4. NIH Policy Manual 3040-2, "Care and Use of Animals in the Intramural Research Program."
5. Public Health Service "Policy on Humane Care and Use of Laboratory Animals," revised September, 1986.
6. 1993 "Report of the AVMA Panel on Euthanasia," JAVMA Vol. 202, No. 2,pp. 229-249, 1993 and updates.

PART A: ADMINISTRATIVE DATA

The requested information identifies the Principal Investigator and Project Title. Indicate if this is an initial Animal Study Proposal or a renewal. If this is a renewal, cite the original proposal number. **Modifications to proposals are required to be submitted for ACUC review and approval for any significant change in the proposal.** Modifications should be submitted to the ACUC by using the NCI Animal Study Proposal Modification Form identifying the significant changes in the proposal.

PART B: ANIMAL REQUIREMENTS

This section requests identification of the species and the strain/stock designation of the animal. Indicate the proposed location for animal holding (building and room), and the research location if it differs from the holding location. If animals will be housed in more than one facility, indicate the percentage of animals in each facility. State the maximum number of animals to be housed at any one time. Indicate the number of animals to be used during each of the three years of the approval period and the total number of animals to be used.

PART C: STUDY OBJECTIVES

Describe the intent of the study as it relates to human or animal health, the advancement of basic scientific knowledge, or the good of society **using non-technical language**.

PART D: RATIONALE FOR ANIMAL USE

1) Explain your rationale for animal use. Why can't cell cultures, computer simulations or other non-animal models be used in place of animals in the study? 2) Justify the appropriateness of the species. Describe the biological characteristics that are essential to the study and why other species are not suitable. 3) Justify the number of animals to be used. Describe the rationale used either by experimental design, past usage levels for harvesting procedures or anticipated levels for propagation or production needs.

PART E: DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

Provide the requested information. Use additional sheets if necessary. Experimental endpoints must be used to define when experimental animals are to be euthanized or provided therapeutic relief. Use of death as an endpoint is discouraged unless a scientific rationale is presented. See http://camp.nci.nih.gov/science/olar/asb/ncipolcy/humanecn.htm.

PART F: SURVIVAL SURGERY

Describe the surgical procedures to be performed, including aseptic technique utilized. Indicate who will perform the surgery and their qualifications or experience. Indicate the location and list requirements for postoperative care and identify the person responsible for this care. Aseptic technique and specialized surgical facilities are required for survival surgery proposed in rabbits and other higher species such as cats, dogs, and nonhuman primates. Survival surgery on rodents should be performed using aseptic technique in suitably prepared areas outside of animal holding rooms. Survival surgery is defined as a surgical procedure from which the animal is allowed to recover from anesthesia. Major survival surgery is defined as any surgical intervention that penetrates a body cavity or has the potential for producing a permanent handicap in an animal that is expected to recover. Non-survival surgery is a surgical procedure after which the animal is euthanized prior to recovery from anesthesia. See http://oacu.od.nih.gov/arac/surguide.htm.

PART G: PAIN OR DISTRESS CATEGORY

See Guidelines for Pain/Distress Classification as separate help page for definitions and guidelines.

For Category 2 or 3 procedures, provide a narrative description of the methods and sources used to determine that alternatives to painful procedures are not available, whether or not the pain or distress is alleviated. Examples include, but are not limited to the following:

- Databases searched and the key words used in the searches. Include the date of the search, key words used, and the period covered. Examples include: AGRICOLA, AIDSLINE, MEDLINE, PREX, AND TOXLINE.
- Pertinent references, bibliographies, or publications.
- Information services utilized. Examples include:
  Animal Welfare Information Center, USDA at http://www.nal.usda.gov/awic/
  NIH Library at 496-2184
- Consultation with individuals having expertise in the field of investigation.

PART H: ANESTHESIA, ANALGESIA, TRANQUILIZATION

For animals indicated in Category 2, Part G., specify the use of any anesthetics, analgesics, sedatives or tranquilizers to be used. Include the name of the agent(s), the dosage and route of administration. Please see the following URL: http://camp.nci.nih.gov/science/olar/asb/invguide/sec-17.htm.

PART I: METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

Indicate method used and, if a parenteral agent is used, specify the dosage and route of administration. Methods which are not consistent with the recommendations of the AVMA Panel on Euthanasia, such as, cervical dislocation or decapitation without anesthesia must be justified in writing. See http://oacu.od.nih.gov/ARAC/euth/avmaeu1.htm and http://camp.nci.nih.gov/science/olar/asb/ncipolcy/humanecn.htm#ChemicallyUncontaminated.

PART J: HAZARDOUS AGENTS

This section must be completed if hazardous material or radionuclides will be used in animals. All documents (Recombinant DNA Documents, Human Pathogen Registration Documents, and/or Material Data Safety Sheets) must be attached to the proposal if such hazards are proposed.

Use of hazardous agents requires the concurrence of the safety representative in Parts J and O.

PART K: BIOLOGICAL MATERIAL/ANIMAL PRODUCTS

Biological material and animal products (cell lines, tissues, and tumors) destined for use in microbiologically defined rodent facilities must be MAP, RAP, or HAP (Mouse, Rat or Hamster Antibody Production) tested prior to introduction unless they are sterile or attenuated. A copy of the test results must be attached to the Animal Study Proposal.

PART L: TRANSPORTATION

Copies of the NIH Transportation Guidelines are available from the NCI Animal Sciences Branch, Building 31, Room 4A34, 496-1866 or see http://oacu.od.nih.gov/ARAC/tranport.htm and http://oacu.od.nih.gov/ARAC/transp10.htm for the Clinical Center.

PART M: SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

List any special housing, animal care, or safety requirements. List any other requirements that the animal facility manager may need to consider. Potential concerns include importation of animals; specialized housing, lighting, feed, or water; a need for non-routine veterinary care; use and storage of specialized pieces of equipment; and, special off-hour or weekend/holiday requirements.

PART N: PRINCIPAL INVESTIGATOR CERTIFICATIONS

Certifications required by NIH Policy or U.S. law.

PART O: CONCURRENCES

It is the responsibility of the Principal Investigator to obtain the signature of the Lab/Branch Chief. If the Principal Investigator is a Laboratory or Branch Chief, the proposal must be signed by the Division Director or next higher level of scientific review authority.

Principal Investigators **utilizing facilities in Bethesda** should then submit the proposal to the Animal Sciences Branch, Building 31, Room 4A34, which provides the “Attending Veterinarian” review, coordinates the safety representative review and coordinates committee action.

Principal Investigators **utilizing facilities in FCRDC** should then submit the proposal to the FCRDC Animal Care and Use Committee, Building 428, Room 52 which provides the “Attending Veterinarian” review, coordinates the safety representative review and coordinates committee action.

PART P : For use by ACUC.

U.S. Interagency Research Animal Committee

U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING. RESEARCH AND TRAINING

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires in vivo experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vivo biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress , and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purpose of teaching or demonstration.

[1]For guidance throughout these Principles the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

10/16/84
IRAC

NATIONAL CANCER INSTITUTE

Animal Study Proposal

Leave Blank:

Proposal # _____

Final Approval _____

A. ADMINISTRATIVE DATA

Principal Investigator _____ Lab/Branch _____

Division _____ E-Mail Address _____

Co-Principal Investigator(s)/Technician(s) _____

Building/Room/MSC _____ - _____ - _____ Telephone _____ FAX Number _____

Project Title _____

Initial Submission ☐ Renewal ☐ of Proposal Number _____

List the names of other individuals authorized to conduct procedures involving animals under this proposal:

B. ANIMAL REQUIREMENTS

Species _____ Age/Weight/Size _____ Sex _____ Source _____

☐ Please check box if this is a dog or primate proposal.

Stock or Strain _____

☐ Please check box if continued on Page 7.

Animal Holding/Research Location(s) _____

☐ Please check box if continued on Page 7. If more than one location indicate the percentage of animals in each facility.

Number of Animals To Be Used: _____ (Year 1) , _____ (Year 2) , _____ (Year 3) = _____ (Total)

Maximum Number of Animals to be Housed at Any One Time _____

C. STUDY OBJECTIVES: Briefly describe **in non-technical language** the objective(s) of the study.

☐ Please check box if continued on Page 8.

D. RATIONALE FOR ANIMAL USE: I) Explain your rationale for animal use. 2) Justify the appropriateness of the species. 3) Justify the number of animals to be used.

☐ Please check box if continued on Page 8.

E. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Describe the experimental design as it relates to the number of animals indicated in Part B. Specify animal procedures including inoculations (sites, substances, dosages, and schedules), blood withdrawals (volume, frequency, and withdrawal sites), surgical procedures (provide details in Part F.), radiation (dosage and schedule), tail biopsies, and methods of restraint. State what resultant effects, if any, the animals are expected to experience. Euthanasia criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation, or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. Use of death as an endpoint must be specifically justified.

☐ Please check box if continued on Page(s) 9-10.

How will animals be identified (i.e., cage card, collar, etc.) ? _____

F. SURVIVAL SURGERY: If proposed, complete the following:

1. Identify and briefly describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized.

☐ Please check box if continued on Page 11.

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed? Building and Room? _____ / _____

4. Describe post-operative care required and identify the responsible individual.

☐ Please check box if continued on Page 11.

5a. Has major survival surgery been performed on any animal prior to its use on this study? ___ Yes ___ No ☐ Please check box if continue on Page 12

5b. Will more than one major survival surgery be performed on an animal while on this study? ___ Yes ___ No

**** If the answer to question a. or b. is yes, an explanation and justification must be provided.***

G. PAIN OR DISTRESS CATEGORY: The ACUC is responsible for applying U.S. Government Principal IV. Contained in this proposal "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Check the appropriate category and indicate the approximate number of animals in each. The sum should equal the total from Part B.

NUMBER OF ANIMALS

- ☐ **Category 1** - Minimal, Transient, or No Pain or Distress _____
- ☐ **Category 2** - Pain or Distress Relieved by Appropriate Measures _____
- ☐ **Category 3** - Unrelieved Pain or Distress*** _____

***** IF ANIMALS ARE INDICATED IN CATEGORY THREE, A WRITTEN SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE APPROPRIATE USE OF ANESTHETICS, ANALGESICS, SEDATIVES, OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED IN THIS STUDY. PLEASE COMPLETE THE EXPLANATION FOR CATEGORY THREE. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. NOTE: THIS CATEGORY THREE FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.**

☐ Please check box if continued on Page 12.

Describe your consideration of alternatives to procedures listed for Category 2 and 3 that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] delineate the methods and sources used in the search below. Database references must include databases searched, the date of the search, period covered, and keywords used. **See instructions for Part G for methods other than database searches.**

☐ Please check box if continued on Page 13.

H. ANESTHESIA, ANALGESIA, TRANQUILIZATION: For animals indicated in Category 2, Part G., specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, the route, and schedule of administration.

☐ Please check box if continued on Page 13.

I. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method and if a parenteral agent is proposed, the dosage and route of administration.

J. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of the NCI or FCRDC safety representative in Part O. **Registration Documents are required** to be attached for the use of recombinant DNA or potential human pathogens. Material Data Safety Sheets are also required to be attached for the use of Hazardous Chemicals or Drugs.

	AGENT-FULL NAME	DOSE	ROUTE	FREQUENCY	DURATION
1. Radioisotopes Yes ____ No ____					
2. Biological/Infectious Agents Yes ____ No ____					
3. Hazardous Chemicals or Drugs Yes ____ No ____					
4. Recombinant DNA Yes ____ No ____					

ADDITIONAL SAFETY CONSIDERATIONS (TO BE COMPLETED BY SAFETY OR RADIATION SAFETY REPRESENTATIVE)

1. Study to be conducted at Animal Biosafety Level _____

2. Practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study to include methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity:

Safety/Radiation Safety Representative's Initials _____

K. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS: (i.e., tumors, cell lines)

1. Specify Material _____

2. Source _____ Material Sterile or Attenuated? _____ Yes _____ No

3. Material MAP/RAP/HAP Tested? _____ Yes (Attach copy of results) _____ No

4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the facilities listed in Section B and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____
Principal Investigator's Initials

L. TRANSPORTATION: Transportation of animals must conform to all NIH and facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be used, including route and elevator for transporting in the Clinical Center.

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY: List any non-standard housing or animal care requirements, i.e., special caging, water or feed, or waste disposal.

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH Investigator training course.

   Year of Course Attendance _____ Location _____ (NIH or FCRDC)

2. I certify that the research proposal herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal who have substantial animal contact are participating in the NIH Animal Exposure Surveillance Program or FCRDC Occupational Medical Program. Call OMS at 496-4411 to enroll at NIH.

4. I certify that the individuals listed in Part A are authorized to conduct procedures involving animals under this proposal, and that they have attended an approved (NIH or FCRDC) investigator training course and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.

5. **FOR ALL CATEGORY 2 AND 3 PROPOSALS (See Section G):** I certify that I have reviewed pertinent scientific literature and the sources and/or databases as noted in Section G and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

6. I will obtain approval from the ACUC before initiating any significant changes in this study.

Principal Investigator: Signature _____ Date _____

O. CONCURRENCES: [PROPOSAL NUMBER (Leave Blank)]

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a laboratory or branch chief.

Name _____ Signature _____ Date _____

LEAVE BLANK - FOR USE BY ACUC ONLY

Safety or Radiation Safety certification of review and approval. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

(*See Section J for safety considerations*)

COMMENTS:

Facility Manager certification of resource availability in the indicated facility to support the proposed study.

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

COMMENTS:

Facility Veterinarian Certification of review:

Name _____ Signature _____ Date _____

Name _____ Signature _____ Date _____

Attending Veterinarian certification of review:

Name _____ Signature _____ Date _____

P. FINAL APPROVAL: Certification of review and approval by the:

- ☐ **DBS ACUS**
- ☐ **DCS ACUS**
- ☐ **FCRDC ACUC**

ACUC/
ACUS Chair _____ Signature _____ Date _____

COMMENTS:

Distribution: Principal Investigator
Facility Manager
ACUC Files

B. STOCK OR STRAIN: (Continuation Page)

B. ANIMAL HOLDING/RESEARCH LOCATION(S): (Continuation Page)

C. STUDY OBJECTIVES: (Continuation Page)

D. RATIONALE FOR ANIMAL USE: (Continuation Page)

E. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: (Continuation Page)

E. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: (Continuation Page)

F. SURVIVAL SURGERY, PART 1: (Continuation Page)

F. SURVIVAL SURGERY, PART 4: (Continuation Page)

F. SURVIVAL SURGERY, PART 5: (Continuation Page)

G. PAIN OR DISTRESS CATEGORY - JUSTIFICATION FOR CATEGORY 3: (Continuation Page)

The Category 3 justifications accompany the NIH Annual Report to the USDA and along with the animal study proposal are available under the Freedom of Information Act.

G. ALTERNATIVES TO PROCEDURES: (Continuation Page)

H. ANESTHESIA, ANALGESIA, TRANQUILIZATION: (Continuation Page)

ADDENDUM TO NCI ANIMAL STUDY PROPOSAL FORM (NIH-2643-1)

EXERCISE FOR DOGS

The plan providing dogs with the opportunity to exercise or housing them in compatible groups developed for the animal holding location indicated in Section B is appropriate for animals used under this proposal.

YES _____ **NO** _____ If No, provide specific scientific justification:

☐ Please check box if continued on Page 2 of this Addendum.

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING OF NON-HUMAN PRIMATES

The plan providing social grouping and environmental enrichment for nonhuman primates developed for the animal holding location indicated in Section B is appropriate for animals used under this proposal.

YES _____ **NO** _____ If No, provide specific scientific justification:

☐ Please check box if continued on Page 2 of this Addendum.

Signature of Principal Investigator _____ Date _____

EXERCISE FOR DOGS JUSTIFICATION : (CONTINUATION PAGE)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING OF NON-HUMAN PRIMATES JUSTIFICATION : (CONTINUATION PAGE)

NATIONAL CANCER INSTITUTE

Modification to Animal Study Proposal Number _____

Instructions: *All changes must relate to a previously approved proposal. Complete and return to the Animal Sciences Branch, Bldg. 31, Rm. 4A34, or at FCRDC, Bldg. 428, Room 52.*

A. ADMINISTRATIVE DATA

Principal Investigator _____ E-Mail Address _____

Building/Room/MSC _____ Telephone _____ FAX number _____

Additions/Deletions of individuals (specify) authorized to conduct procedures involving animals under this proposal:

B. NEW ANIMAL REQUIREMENTS:

Write NA (not applicable) **in each blank** if there are no changes.

Species _____ Stock/Strain _____

Animal Holding/Research Location _____

Number of animals to be added for each year remaining on the study

Year 1	Year 2	Year 3
_____	_____	_____

Rationale for the above changes:

C. MODIFICATION OF EXPERIMENTAL DESIGN OR ANIMAL PROCEDURES:

Describe any changes in the experimental design, procedures or materials to be used. **(Use additional pages if necessary.)**

☐ Please check box if continued on Page 2 of this Modification.

Rationale for the modifications:

☐ Please check box if continued on Page 2 of this Modification.

D. HAZARDOUS AGENTS:

Please describe any changes in usage of hazardous agents. Registration Documents are required to be attached for the added use of recombinant DNA or potential human pathogens.

E. SIGNATURES:

Principal Investigator: Signature _____ Date _____

Safety Representative certification of review and approval. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

APPROVAL:

ACUC/ACUS Chair _____ Signature _____ Date _____

(Continuation Page)

C. MODIFICATION OF EXPERIMENTAL DESIGN OR ANIMAL PROCEDURES:

Rationale for the Modifications: